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RTX Healthcare

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirement of 21 CFR 807.92


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**Date of summary:** July 10, 2007

**Common Name:** Physiological Transmitter and Receiver
**Trade name:** RTX3370

**Classification name:** 21 CFR 870.2910 Physiological Signal Transmitter And Receiver.
**Classification no:** DRG

**Predicate Device:**
The RTX3370 device is substantially equivalent to the following predicate device:
510(k) number: K062304
Device name: DLM112 Daylink Monitor
Applicant: RTX Healthcare

**Submission Device Description:**
The RTX3370 telemedicine device performs transmission of physiological patient information to and from wireless, infrared and cabled patient monitors, and a remote data server healthcare facility using standard digital communication technologies and protocols. The RTX3370, with its build-in modem, transmits data using the public switched telephone network.
The RTX3370 screen, displays the information or questions about vital signs, symptoms and behaviors sent by the patient's healthcare provider, and allows the patient to respond via four large buttons
The RTX3370 device is not used directly on a patient, and poses no significant risk to the patient or other people within the patient's home.

**Intended use and indications for use:**
The RTX3370 is for use in non-clinical settings (such as the home), as an accessory device that is intended to be a communication tool to enable health care providers to receive historical patient information. It is intended to be used in combination with a variety of external devices. The RTX3370 serves as the remote communication link between

compatible external devices, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management centre or with the healthcare/wellness provider or other out of hospital caregivers. The purpose is to collect and transmit selected medical information (such as weight, blood pressure, blood glucose) over a normal residential telephone line.
The RTX3370 does not measure, interpret or make any decisions on the vital data that it conveys.

**Substantial Equivalence Comparison table:**

| Item | | Submission device | Predicate device K062304 (RTX Healthcare) |
|---|---|---|---|
| 1 | Intended use / Indication for use | See section 3 | Same |
| 2 | Intended users | Home users and healthcare providers. | Same |
| 3 | Site of use | Typically for use in patient's home, placed on a normal table. | Same |
| 4 | System description | Telemedicine device that is working as hub/gateway sending measured data from compatible patient monitors to a compatible data server. | Same |
| 5 | Connection to patient monitors | Wireless and cable connection between the patient monitors and the hub/gateway. | Same |
| 6 | Transmission | Residential telephone line | Same |
| 7 | Patient Interactions | Monochrome display and push buttons for collection of patient typed data | Colour display and push buttons for collection of patient typed data. |
| 8 | Measurements taken | Blood pressure, weight, ECG, Blood glucose and other measurements provided from compatible monitor devices. | Same |
| 9a | Contra indications and warnings | The device is not for emergency calls, and may not be used to send any real-time alarms or time-critical data. | Same |
| 9b | Contra indications and warnings | All patient medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional. | Same |
| 9c | Contra indications and warnings | The device is not for use in systems which substitute for medical care. | Same |
| 9d | Contra indications and warnings | The device is not for use in systems set up for patients who need direct medical supervision or who might need emergency intervention. | Same |

| | | | |
|---|---|---|---|
| 10 | Wireless link between patient monitors and the gateway | Short range radio system using Bluetooth technology. | Same |
| 11 | Device specifications | See section 7 | Dimensions and weight changed. |

**Discussion of similarities and differences:**

***Item 1 to 6:*** No differences.

***Item 7:*** The submission device is equipped with a colour display instead of the monochrome display on the predicate device. The size of the visible display area is almost the same and the use of the display in interaction with the user is based on the same principles.
The push button layout is different on the submission device compared to the predicate device, but with the same functionality seen from the user. An extra Info key is added to support the user interaction.

***Item 8 to 10:*** No differences.

***Item 11:*** The submission device and the predicate device are different on the following specifications:

| Specification | Submission device | Predicate device |
|---|---|---|
| Dimensions | (W x L x H): 145 x 125 x 75 mm / 5.7 x 4.9 x 2.9 inches | (W x L x H): 156 x 145 x 70 mm / 6.2 x 5.7 x 2.8 inches |
| Weight | 295 g / 11 oz including power supply adapter | 425 g / 15 oz including power supply adapter |

The visual design on the submission device is different than the predicate device.
Mechanics materials used in both the submission device and the predicate device are common materials used in house hold electronic, mobile phones etc. The mechanic parts in the submission device are addressed in the risk analysis, and does not bring additional or new risks compared to the predicate device.

**Performance data:**
The RTX3370 device has been tested to meet the requirements of the following standards and regulations used as acceptance criteria:
IEC 60601-1, IEC 60601-1-2, EN980, FCC part 15 and FCC Part 68.
Risk management is performed according to ISO14971:2000 using FMEA.
Based on the fact that the performance comparison of the predicate device and the submission device show that the differences are minor and causes no harm to the user, and the fact that the intended use and indication for use is the same, it was early in the project decided to focus on verification and internal validation instead of large scale validation in form of clinical investigation.
Verification and validation testing activities are successfully conducted according to the company's design control processes to establish performance and reliability characteristics of the device.

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**Conclusion**

The RTX3370 is substantially equivalent in technology, features, labeling and indications for use compared to the predicate device cleared by FDA.

Verification and validation activities demonstrate that safety and effectiveness are acceptable and comparable to the performance of the predicate device, justifying 510(k) clearance of the modified device RTX3370

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2007

RTX Healthcare A/S
c/o Mr. Niels O. Anderson
Engineering Manager
Stroemmen 6
Noerresundby
DK-9400, Denmark

Re: K071953
RTX3370
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: July 10, 2007
Received: July 16, 2007

Dear Mr. Anderson:

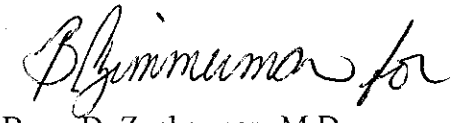
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071953

4. Indications for use statement

# Indication for Use Statement

**510(k) Number (if known):**

**Device name:** RTX3370

The RTX3370 is for use in non-clinical settings (such as the home), as an accessory device that is intended to be a communication tool to enable health care providers to receive historical patient information. It is intended to be used in combination with a variety of external devices. The RTX3370 serves as the remote communication link between compatible external devices, and the compatible healthcare facility at another location. The healthcare facility could be at a disease management centre or with the healthcare/wellness provider or other out of hospital caregivers. The purpose is to collect and transmit selected medical information (such as weight, blood pressure, blood glucose) over a normal residential telephone line.
The RTX3370 does not measure, interpret or make any decisions on the vital data that it conveys.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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10(k) Number K071953